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ATTORNEY DOCKET NO. 00537/184002 - 066/US/PCT/US

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Alan F. Feeney

Printed name of person mailing correspondence

Signature

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: FRANCIS X. IGNATIOUS

Serial No.: 09/830,945

Filed: July 12, 2001

Title: LACTONE BEARING ABSORBABLE POLYMERS

Art Unit: 1615

Examiner: VENKAT, JYOTHSNA A

Commissioner for Patents  
Washington, D.C. 20231

TRANSMITTAL LETTER AND AUTHORIZATION TO PAY FEE

Transmitted herewith is a Response to Restriction/Election Requirement mailed October 2, 2002; a Petition for Extension of Time with a Certificate of Mailing noted thereon; and Fee authorization (2 copies) together with an Acknowledgment Postcard.

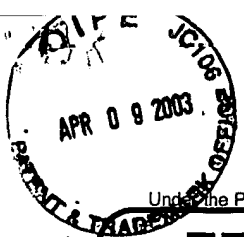
The Commissioner is hereby authorized to charge the fee due under 37 CFR 1.136(a) for the Requested Five (5) Month Extension to Deposit Account No. 50-0590. Applicant believes that no other fees are due. However, the Commissioner is hereby authorized to charge any other fees that may be deemed to be due or to credit any overpayments to Deposit Account 50-0590. A duplicate copy of this letter is transmitted herewith.

Respectfully submitted,  
Biomeasure, Inc.

Date: 4-1-2003

Alan F. Feeney  
Attorney for Applicant(s)  
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# FEE TRANSMITTAL for FY 2003

Patent fees are subject to annual revision.

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$)**1,970.00**

## Complete if Known

Application Number **09/830,945**  
Filing Date **July 12, 2001**  
First Named Inventor **Francis X. Ignatious**  
Examiner Name **Venkat, Jyothsna A.**  
Art Unit **1615**  
Attorney Docket No. **00537/184002 - 066/US/PCT/US**

## METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None

☒ Deposit Account:

Deposit  
Account  
Number  
Deposit  
Account  
Name

**50-0590**

**BIOMEASURE, INCORPORATED**

The Commissioner is authorized to: (check all that apply)

☒ Charge fee(s) indicated below ☒ Credit any overpayments  
☒ Charge any additional fee(s) during the pendency of this application  
☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.

## FEE CALCULATION

### 1. BASIC FILING FEE

Large Entity Fee Code (\$)	Small Entity Fee Code (\$)	Fee Description	Fee Paid
1001 740	2001 370	Utility filing fee	
1002 330	2002 165	Design filing fee	
1003 510	2003 255	Plant filing fee	
1004 740	2004 370	Reissue filing fee	
1005 160	2005 80	Provisional filing fee	
SUBTOTAL (1) (\$)			

### 2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

Total Claims  -20\*\* =  X  =   
Independent Claims  -3\*\* =  X  =   
Multiple Dependent  =

Large Entity Fee Code (\$)	Small Entity Fee Code (\$)	Fee Description
1202 18	2202 9	Claims in excess of 20
1201 84	2201 42	Independent claims in excess of 3
1203 280	2203 140	Multiple dependent claim, if not paid
1204 84	2204 42	** Reissue independent claims over original patent
1205 18	2205 9	** Reissue claims in excess of 20 and over original patent
SUBTOTAL (2) (\$)		

\*\*or number previously paid, if greater; For Reissues, see above

## FEE CALCULATION (continued)

### 3. ADDITIONAL FEES

Large Entity Small Entity

Fee Code (\$)	Fee Code (\$)	Fee Description	Fee Paid
1051 130	2051 65	Surcharge - late filing fee or oath	
1052 50	2052 25	Surcharge - late provisional filing fee or cover sheet	
1053 130	1053 130	Non-English specification	
1812 2,520	1812 2,520	For filing a request for <i>ex parte</i> reexamination	
1804 920*	1804 920*	Requesting publication of SIR prior to Examiner action	
1805 1,840*	1805 1,840*	Requesting publication of SIR after Examiner action	
1251 110	2251 55	Extension for reply within first month	
1252 400	2252 200	Extension for reply within second month	
1253 920	2253 460	Extension for reply within third month	
1254 1,440	2254 720	Extension for reply within fourth month	
1255 1,960	2255 980	Extension for reply within fifth month	
1401 320	2401 160	Notice of Appeal	
1402 320	2402 160	Filing a brief in support of an appeal	
1403 280	2403 140	Request for oral hearing	
1451 1,510	1451 1,510	Petition to institute a public use proceeding	
1452 110	2452 55	Petition to revive - unavoidable	
1453 1,280	2453 640	Petition to revive - unintentional	
1501 1,280	2501 640	Utility issue fee (or reissue)	
1502 460	2502 230	Design issue fee	
1503 620	2503 310	Plant issue fee	
1460 130	1460 130	Petitions to the Commissioner	
1807 50	1807 50	Processing fee under 37 CFR 1.17(q)	
1806 180	1806 180	Submission of Information Disclosure Stmt	
8021 40	8021 40	Recording each patent assignment per property (times number of properties)	
1809 740	2809 370	Filing a submission after final rejection (37 CFR 1.129(a))	
1810 740	2810 370	For each additional invention to be examined (37 CFR 1.129(b))	
1801 740	2801 370	Request for Continued Examination (RCE)	
1802 900	1802 900	Request for expedited examination of a design application	

Other fee (specify) \_\_\_\_\_

\*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$)**1,970.00**

## SUBMITTED BY

Name (Print/Type) **Alan F. Feeney** Registration No. **43,609** Telephone **508/478-0144**  
Signature *Alan F. Feeney* Date **4-1-2003**

**WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.**

This collection of information is required by 37 CFR 1.17 and 1.27. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

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Attorney Docket No. 00537/184002  
066/US/PCT/US

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415-03

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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IN RE APPLICATION OF:

**FRANCIS X IGNATIUS**

APPLICATION NO.: **09/830,945**

FILED: **July 12, 2001**

FOR: **LACTONE BEARING ABSORBABLE  
POLYMERS**

-----  
Assistant Commissioner of Patents  
Washington, D.C. 20231

Sir:

EXAMINER: **VENKAT, JYOTHSNA A.**

ART UNIT: **1615**

I hereby certify under 37 CFR 1.8(a) that this  
correspondence is being deposited with the United  
States Postal Service as first class mail with  
sufficient postage on the date indicated below and  
is addressed to the Assistant Commissioner of  
Patents, Washington, D.C. 20231.  
Date of Deposit: April 1, 2003

RESPONSE TO RESTRICTION REQUIREMENT

Responsive to the action mailed October 2, 2002 (Paper No. 7)(hereinafter "the Action"), Applicant respectfully requests consideration of the following remarks and reconsideration of the restriction delineated in the Action.

The instant application is a national stage application under 35 U.S.C. §371 of PCT International Application PCT/US99/25706. As such, unity of invention, rather than restriction, practice is applicable. See MPEP §1893.03(d). Rule 13 (Unity of Invention) of the Regulations under the PCT state that the requirement of unity is fulfilled when "there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features." Rule 13.2, Regulations under the PCT

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Unity of Invention practice, is also governed by MPEP §1893.03(d), which states in part:

*When making a lack of unity invention requirement, the Examiner **must** (1) list the different groups of claims and (2) explain why each group lacks unity with each other group (i.e., why there is no single general inventive concept) **specifically describing the unique** special technical feature in each group.*

(Emphasis added) MPEP §1893.03(d).

Applicant respectfully contends that the Examiner has not met the burden of the 2<sup>nd</sup> prong of the above-stated requirement when requiring the restriction of an application. The reasons provided by the Examiner for the lack of unity are as follows:

The special technical feature of group I is a polymer where as [sic] in group II the technical feature is complex [sic] and its use in pharmaceutical compositions as well as sustained release compositions which is not present in Group I and the special technical feature of group III is treatment of a disease, which is, not present in group I or group II.

The Examiner cited no art in support of the creation of the alleged restriction groupings. The rationale provided by the Examiner is not justification for restricting the present application. The cited differences between the three designated groups, i.e., "a polymer", "a complex" and "a treatment of a disease", are not "unique special technical features" as envisioned by the Rules of Unity of Invention.

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Applicant respectfully submits that the three inventions as delineated in the Action meet the criterion of relating to a single inventive concept. As stated at MPEP §1893.03(d),

A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. The expression special technical features is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art.

It is apparent, as detailed in the specification of the instant application, that claims 1-17 are directed to **a polymer bearing a thermodynamically stable lactone ring considered to be non-polymerizable** under normal conditions. Claims 18-22 are directed to a complex comprised of **a polymer bearing a thermodynamically stable lactone ring considered to be non-polymerizable** under normal conditions and a therapeutic agent. Claims 23-24 are directed to a sustained release composition composed of a complex comprised of **a polymer bearing a thermodynamically stable lactone ring considered to be non-polymerizable** under normal conditions and a therapeutic agent. Claims 25-26 are directed to a pharmaceutical composition having a sustained release composition composed of a complex comprised of **a polymer bearing a thermodynamically stable lactone ring considered to**

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**be non-polymerizable** under normal conditions and a therapeutic agent. Claims 27-30 are directed to a method of medicinal treatment by administering a pharmaceutical composition having a sustained release composition composed of a complex comprised of **a polymer bearing a thermodynamically stable lactone ring considered to be non-polymerizable** under normal conditions and a therapeutic agent to patient in need thereof. Applicant contends that the special technical feature to all the claims is **a polymer bearing a thermodynamically stable lactone ring considered to be non-polymerizable**. Applicant further maintains that the claims are analogous to Examples 1 and 15 of Annex B Part 2 of the PCT Administrative Instructions as amended July 1, 1992 contained in Appendix AI of the MPEP. As such, the claims do exhibit "unity" and should be maintained in the present application.

The Examiner goes on to state that "the different species would require completely different searches...and [since there] is no expectation that the search would be coextensive...an undue search burden [is put upon the Examiner]." Applicant contends that the Examiner has applied conditions inconsistent with PCT Unity of Invention criteria and has instead impermissibly invoked U.S. Restriction Rules. Even if the U.S. restriction rules were

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applicable, which they are not, the Examiner deviates from the criteria for restriction as established by the MPEP regarding distinct inventions. See MPEP §803. Applicant respectfully submits that there is no requirement under the rules that the search for any claim or groups of claims be "co-extensive" with the search required for any other claim or group of claims, as the Examiner contends. The MPEP in §808.2, requires that when establishing a need for the restriction of related inventions, the Examiner must show "[the necessity] to search for one of the distinct subjects in places where no pertinent art to the other subject exists." As Applicant has demonstrated, *infra*, there is very substantial, if not complete, overlap between the searchable subject matter with respect to Group I and the searchable subject matter with respect to Groups II and III. Applicant submits that, contrary to the Examiner's opinion, no serious burden will arise from examining Group I concurrently with Groups II and III. As discussed *infra*, all of the designated groups share the technical feature of **a polymer bearing a thermodynamically stable lactone ring considered to be non-polymerizable**. Thus, any search of the subject matter of either groups II or III, i.e., a pharmaceutical containing **a polymer bearing a thermodynamically stable lactone ring considered to be non-**

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**polymerizable** or use of said pharmaceutical to treat a medical condition, necessarily must contemplate the subject matter of Group I. Conversely, any search performed with respect to Group I, would necessarily involve significant overlap with a search performed with respect to the other Groups. Surely, the Examiner does contend that a search of a pharmaceutical containing a polymer bearing a thermodynamically stable lactone ring considered to be non-polymerizable (Group II), would not only uncover art pertinent to the patentability of the polymer bearing a thermodynamically stable lactone ring considered to be non-polymerizable, itself (Group I), but also the use of the pharmaceutical to treat or prevent a disease or condition (Group III). The Examiner's allegation that there is "no expectation that the search [sic] would be coextensive" lacks merit.

For the foregoing reasons, the Applicant submits that the restriction made in the Action was improper and respectfully requests reconsideration of that restriction and a delineation of reasoned support for distinguishing each group ultimately determined as lacking unity with each other group, as required under MPEP §1893.03(d).



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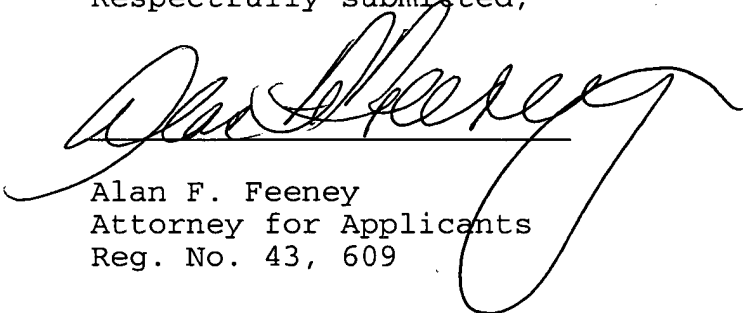
In compliance with 37 C.F.R. §1.143, Applicant elects the invention of Group I drawn to a polymer bearing a non-polymerizable lactone ring and elects a polyester (a member of the Markush list of monomer sources comprising the copolymer of claim 1) as the species of polymer. The election is made with traverse.

Prompt and favorable action is earnestly solicited.

Please apply any charges of credits to Deposit Account No. 50-0590 referencing Attorney Docket No. 066/US/PCT/US.

Respectfully submitted,

Date: 4-1-2003

  
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